DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 22 2000

Norav Medical Ltd.
c/o Mr. Steve Springrose
Springrose Partners, LLP
12505 58th Avenue N.
Plymouth, MN 55442

Re: K000404
PC ECG 1200 ECG and Stress Electrocardiography System
Regulatory Class: II (two)
Product Code: 74 MWI
Dated: September 14, 2000
Received: September 15, 2000

Dear Mr. Springrose:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER ( IF KNOWN) K000404

DEVICE NAME: ECG and Stress Electrocardiography System

INDICATIONS FOR USE:

ECG intended use:

ECG is intended to disclose either normal condition or patterns of arrhythmia, myocardial ischemia, rate abnormalities, or features of prognostic value in patients:

1) suspected of cardiac abnormalities, or

2 )in populations of patients at an age or period in which a routine baseline evaluation of ECG characteristics are desired.

3) QT Analysis is useful in the assessment of long QT syndrome (LQTS). In some instances, LQTS can be corrected by pharmacologic therapy. QT analysis is also used to measure QT dispersion, the difference between maximal and minimal QT values. QT dispersion is a measure of the inhomogeneity of ventricular repolarization.

4) The PC ECG 1200 has been tested to measure Heart Rate Variability within 1 millisecond tolerance. The clinical significance of Heart Rate Variability measures should be determined by a physician.

5) The PC ECG 1200 has been tested to measure Late Potential within 1 millisecond tolerance in the time domain, and 1 microvolt tolerance in voltage. The clinical significance of Late Potential measures should be determined by a physician.

Stress testing intended use:

Angina pectoris (chest pain) is a clinical syndrome resulting from myocardial ischemia, indicative of a reduced blood supply to the cardiac muscle. The electrocardiogram may establish the diagnosis of ischemic heart disease if characteristic changes are present. Stress testing is the most widely used method to decide whether this chest pain is related to myocardial ischemia, and thereby coronary artery disease. In stress testing, the contractile capability of the heart muscle is monitored via ECG during patient exercise. Patients are exercised by bicycle, treadmill, or other means while continuously monitoring the ECG. Exercise loads are determined by predefined protocols. The ECG signals are recorded for the resting, exercise and recovery portions of the exercise protocol. The changes in ECG waveforms are compared to the resting ECG records. Although not necessary, most of the commercial stress test systems control the bicycle or treadmill automatically according to the requirements of the chosen protocol.

ST segment monitoring is intended as an aid in the evaluation of myocardial ischemia in patients with known or suspected coronary artery disease. The ST segment algorithm has been tested for accuracy of the ST segment data, and a database has been used as a tool for performance testing. The significance of the ST segment changes must be determined by a physician.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K000404

Prescription Use ✓ OR Over the Counter Use _____

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices

(Optional Format 1-2-96)

510(k) Number _____